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IP DEPARTMENT OF PIPER RUDNICK LLP  
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/939,483

Applicant(s)

DUPRAT ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Applicant's amendment filed 06/01/2004 has been entered. Claims 1-31 and 33 have been cancelled. Claim 32 has been amended, is pending and is currently under consideration.

#### *Priority*

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The current status of all nonprovisional parent applications referenced should be included or updated. The current reference fails to include the updated status of all priority documents.

#### *Sequence Compliance*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequences in Figures 5-7, 8A-8F, 10A-10B, and 11A-11D require SEQ ID Nos in the description of the figures.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must

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provide statements regarding sameness and new matter with regards to the CRF and the “Sequence Listing.” Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claim 32 under 35 USC 101 as being drawn to non-statutory subject matter is withdrawn in light of Applicant’s amendments to the claim.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claim 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record set forth on pages 5-6 of the previous office action mailed 11/28/2003. Applicant’s arguments have been fully considered and are found partially persuasive.

The rejection on the grounds that the breadth of the claims encompass non-mouse species of animals is withdrawn in light of Applicant’s amendments to the claim limiting the scope of the knockout animal to a mouse.

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The rejection based on the failure of the specification to enable the claimed mouse exhibiting any phenotype or failing to exhibit a phenotype at all is maintained. The rejection is based on the fact that the claim does not recite a phenotype for the claimed mouse and therefore encompasses a mouse exhibiting any phenotype, including a wild-type phenotype. Without a recitation of a phenotype in the claims, one would not know when they had attained the claimed mouse or how to use it because it is not known what phenotype the claimed mouse should exhibit.

Applicant has argued that because the protein encoded by SEQ ID NO:5 has been characterized the art of record (specifically Griffiths) establishing the unpredictability of phenotype in transgenic mice is not applicable. Applicant also argues that the phenotype of the mice taught by Griffiths was identified through processes known to those skilled in the art (page 7, paragraph 2). Applicant argues that because the regulation and tissue distribution of the TASK protein (sequence set forth in part by SEQ ID NO:5) are known, the phenotype can be elucidated by the skilled artisan.

In response, the specification has taught that TASK is expressed in a large number of tissues, including brain, lung, prostate heart, kidney, uterus, small intestine, colon, pancreas and placenta (page 18, paragraph 1). The specification teaches functional characterization of TASK by expressing a TASK cRNA in *Xenopus* oocytes and assessing potassium currents using patch clamp assays (pages 19-21). Similar in vitro assays were performed using COS cells (page 21). The specification also teaches assessing regulation of TASK function as a result of altering cellular pH or activation of protein kinase C in vitro (pages 22-23). The specification does not teach any characterization of TASK that would give the skilled artisan any indication of what

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phenotype would occur in vivo in a mouse lacking TASK gene function. The specification merely teaches prophetically, making the claimed mouse and fails to teach the claimed mouse in such a manner that one of skill in the art would know how to use the mouse. Knowing the cellular function of a gene product in vitro does not render predictable the phenotype of a corresponding knockout mouse in vivo. That mouse could be embryonic lethal or could have no phenotype at all. Furthermore, it would require undue experimentation for the skilled artisan to determine the phenotype of the claimed mouse and to determine a use for the mouse exhibiting the phenotype. Having the skills to carry out experimentation does not render that experimentation routine.

Applicant also argued that the teachings of Leonard as they relate to the unpredictability of phenotype in knockout mice do not apply to the claimed mouse. Applicant argues that Leonard taught a mouse comprising a knockout of a pleiotropic gene involved in multiple cellular functions and therefore having pleiotropic phenotypic effects.

In response, the instant specification has taught that the TASK gene is expressed in a multitude of tissues (see above). It cannot be determined how altering potassium concentrations will affect the various tissues in vivo. The phenotypic effects of altering TASK activity in the heart may be very different from those resulting from alteration of TASK activity in the brain. The cellular compositions, ion concentrations, other ion channels and interacting proteins in various tissues and populations of cells are different. Furthermore, the role of the various tissues in the mouse in vivo are different from one another and therefore, the phenotypic effects of knocking out a gene, even one known to have the same activity in different tissues, can be pleiotropic.

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Therefore, Applicant's arguments that the instant specification overcomes the unpredictability of phenotype in knockout mice are not persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claim 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendments to the claims. However, a new grounds of rejection that is necessitated by the amendments appears below.

Claim 32 is unclear because it refers to a mouse that is deficient in the expression of a potassium transport channel encoded by a nucleic acid sequence comprising SEQ ID NO:5. However, SEQ ID NO:5 is not a nucleic acid sequence but is a partial protein sequence.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 32 under 35 U.S.C. 102(b) is withdrawn in light of Applicant's amendments to the claim.

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*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

*Joe Wontak*  
AU1632